

Application No. 10/630,219  
Second Preliminary Amendment

Docket No.: 03-002

### AMENDMENTS TO THE CLAIMS

1. (Currently Amended) A method of manufacturing a lead for implanting in a human body comprising the steps of:

- placing an inner layer of extrusion material on a mandrel;
- placing at least one conductor coated with a layer of extrusion material on the inner layer of extrusion material;
- placing an outer layer of extrusion material over the at least one conductor coated with a layer of extrusion material to form a lead body assembly;
- forming the lead body assembly, wherein the formed lead body assembly contains a unitary wall and wherein the conductors are within the unitary wall;
- attaching at least one electrode to the at least one conductor at a distal end of the lead body; and
- attaching at least one connector to the at least one conductor at a proximal end of the lead body.

2. (Original) The method as claimed in Claim 1 wherein the forming step further comprises the steps of:

- placing heat shrink tubing over the lead body assembly;
- heating the lead body assembly to melt the extrusion material in the lead body assembly;
- compressing the melted extrusion material around the at least one conductor coated with a layer of extrusion material in the lead body assembly;
- cooling the lead body assembly to form the lead body; and removing the heat shrink tubing from the lead body.

3. (Original) The method as claimed in Claim 1 wherein the extrusion material of the inner layer and the extrusion material on the at least one conductor coated with a layer of extrusion material and the extrusion material of the outer layer are formed from the same type of extrusion material.

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4. (Currently Amended) A method of manufacturing a lead body for implantation in a human body comprising the steps of:

placing at least one conductor coated with a layer of extrusion material on a mandrel;  
and

placing an outer layer of extrusion material over the at least one conductor coated with a layer of extrusion material to form a lead body assembly; and  
attaching at least one electrode to said at least one conductor.

5. (Original) The method as claimed in Claim 4 further comprising the steps of:  
placing heat shrink tubing over the lead body assembly;  
heating the lead body assembly to melt the extrusion material in the lead body assembly;

compressing the melted extrusion material around the at least one conductor coated with a layer of extrusion material in the lead body assembly;  
cooling the lead body assembly to form the lead body; and  
removing the heat shrink tubing from the lead body.

6. (Original) The method as claimed in Claim 4 wherein the extrusion material on the at least one conductor coated with a layer of extrusion material and the extrusion material of the outer layer are formed from the same type of extrusion material.

7. (Currently Amended) A method of manufacturing a lead body for implantation into a human body comprising the steps of:

placing an inner layer of extrusion material on a mandrel; and  
placing at least one conductor coated with a layer of extrusion material on the inner layer of the extrusion material on the mandrel; and  
attaching at least one electrode to said at least one conductor.

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8. (Original) The method as claimed in Claim 7 further comprising the steps of:  
placing heat shrink tubing over the lead body assembly;  
heating the lead body assembly to melt the extrusion material in the lead body assembly;  
compressing the melted extrusion material around the at least one conductor coated with a layer of extrusion material in the lead body assembly;  
cooling the lead body assembly to form the lead body; and  
removing the heat shrink tubing from the lead body.
9. (Original) The method as claimed in Claim 7 wherein the extrusion material on the at least one conductor coated with a layer of extrusion material and the extrusion material of the inner layer are formed from the same type of extrusion material.
10. (Currently Amended) A method of manufacturing a lead body for implantation into a human body comprising the steps of:  
providing at least one conductor coated with a layer of extrusion material; and  
placing the at least one conductor coated with a layer of extrusion material on a mandrel to form a lead body assembly; and  
attaching at least one electrode to the at least one conductor near an end of the lead body assembly.
11. (Original) The method as claimed in Claim 10 further comprising the steps of:  
placing heat shrink tubing over the lead body assembly;  
heating the lead body assembly to melt the extrusion material in the lead body assembly;  
compressing the melted extrusion material around the at least one conductor coated with a layer of extrusion material in the lead body assembly;  
cooling the lead body assembly to form the lead body; and  
removing the heat shrink tubing from the lead body.

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12. (Original) A lead for implantation in a human body, the lead comprising:  
a lead body comprising of:  
a unitary wall having an inner portion that forms a lumen; and  
one or more conductors wherein the one or more conductors are spirally wound  
around the lumen and are within the unitary wall;  
at least one electrode located at a distal end of the lead body; and  
at least one connector located at a proximal end of the lead body, wherein the at least  
one connector and at least one electrode are connected by at least one conductor.
13. (Original) The lead as claimed in Claim 12 wherein the unitary wall is  
comprised of extrusion material.
14. (Original) The lead as claimed in Claim 12 wherein no electrical insulation  
material is between the conductors and the unitary wall.
15. (Original) The lead as claimed in Claim 12 further wherein the diameter of the  
lead is no greater than 34 French.
16. (Original) The lead as claimed in Claim 15 further comprising of at least five  
electrodes.
17. (Original) A system for stimulating a portion of a human body, wherein  
the system comprises:  
a source for generating a stimulus; and  
a lead connectable to the source for receiving the stimulus from the source, wherein the  
lead comprises:  
a lead body comprising:  
a unitary wall having an inner portion that forms a lumen; and  
at least one conductor wound around the lumen and within the unitary wall;  
at least one electrode located at a distal end of the lead body; and  
at least one connector located at a proximal end of the lead body, wherein the at least  
one connector and the at least one electrode are connected by the at least one conductor.
18. (Original) The system as claimed in Claim 17, wherein the unitary wall is  
comprised of extrusion material.

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19. (Original) The system as claimed in Claim 17 wherein no electrical insulation material is between the conductors and the unitary wall.

20. (Original) The system as claimed in Claim 17 wherein the diameter of the lead is no greater than 34 French.

21. (Original) The system as claimed in Claim 15 wherein the lead comprises at least five electrodes.

22. (Currently Amended) A method of manufacturing a lead for stimulation of a portion of a human body comprising the steps of:  
placing at least one conductor coated with a layer of extrusion material on a mandrel;  
forming a unitary lead body assembly with a lumen and with at least one conductor within a unitary wall and spirally wound around the lumen;  
attaching at least one electrode to the at least one conductor at a distal end of the lead body; and  
attaching at least one connector to the at least one conductor at a proximal end of the body.

23. (Original) The method as claimed in Claim 22 wherein the step of placing further comprises the steps of placing a first layer of extrusion material on the mandrel.

24. (Original) The method as claimed in Claim 22 wherein the step of forming further comprises the steps of:  
placing heat shrink tubing over the lead body assembly;  
heating the lead body assembly to melt the extrusion material to form a unitary body;  
and  
removing the heat shrink tubing from the lead body.

25. (Original) The method as claimed in Claim 24 further comprising the step of compressing the melted extrusion material around the at least one conductor coated with a layer of extrusion material in the lead body assembly.

26. (Original) The method as claimed in Claim 23 wherein the extrusion material is placed exterior to the at least one conductor.

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27. (Original) The method as claimed in Claim 23 wherein the extrusion material is placed interior to the at least one conductor.

28. (Original) The method as claimed in Claim 27 wherein a second layer of extrusion material is placed exterior to the at least one conductor.

29. (Currently Amended) A method of manufacturing a lead body for implantation in a human body comprising the steps of:

placing an inner layer of extrusion material on a mandrel;  
placing at least one conductor coated with a layer of extrusion material on the inner layer of extrusion material placed on the mandrel; and  
placing an outer layer of extrusion material over the at least one conductor coated with a layer of extrusion material to form a lead body assembly; and  
attaching at least one electrode to the at least one conductor near an end of the lead body assembly.

30. (Previous Presented) The method as claimed in Claim 29 further comprising the steps of:

placing heat shrink tubing over the lead body assembly;  
heating the lead body assembly to melt the extrusion material in the lead body assembly;  
compressing the melted extrusion material around the at least one conductor coated with a layer of extrusion material in the lead body assembly;  
cooling the lead body assembly to form the lead body; and  
removing the heat shrink tubing from the lead body.

31. (Previous Presented) The method as claimed in Claim 29 wherein the extrusion material of the inner layer and the extrusion material on the at least one conductor coated with a layer of extrusion material and the extrusion material of the outer layer are formed from the same type of extrusion material.

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32. (Currently Amended) A lead body assembly for implantation into a human body comprising:

- an inner layer of extrusion material;
- a plurality of conductors wherein each conductor of the plurality of conductors is coated with a layer of extrusion material and wherein each conductor of the plurality of conductors is placed on the inner layer of extrusion material; and
- an outer layer of extrusion material placed over the plurality of conductors; and at least one electrode attached to at least one conductor of said plurality of conductors.

33. (Previous Presented) A lead body assembly as claimed in Claim 32 that has been subjected to heat and compression to form a lead body.

34. (Currently Amended) A lead body assembly for implantation in a human body comprising:

- a plurality of conductors wherein each conductor of the plurality of conductors is coated with a layer of extrusion material;
- a plurality of electrodes, each electrode of said plurality of electrodes coupled to a conductor of said plurality of conductors; and
- an outer layer of extrusion material placed over the plurality of conductors.

35. (Previous Presented) A lead body assembly as claimed in Claim 34 that has been subjected to heat and compression to form a lead body.

36. (Currently Amended) A lead body assembly for implantation into a human body comprising:

- an inner layer of extrusion material; and
- a plurality of conductors wherein each conductor of the plurality of conductors is coated with a layer of extrusion material and wherein each conductor of the plurality of conductors is placed on the inner layer of extrusion material;
- a plurality of electrodes, each electrode of said plurality of electrodes coupled to a conductor of said plurality of conductors.

37. (Previous Presented) A lead body assembly as claimed in Claim 36 that has been subjected to heat and compression to form a lead body.

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38. (Currently Amended) A lead body assembly for implantation into a human body comprising:

a plurality of conductors wherein each conductor of the plurality of conductors is coated with a layer of extrusion material; and

a plurality of electrodes, each electrode of said plurality of electrodes coupled to a conductor of said plurality of conductors.

39. (Previous Presented) A lead body assembly as claimed in Claim 38 that has been subjected to heat and compression to form a lead body.

40. (Currently Amended) A method of manufacturing a lead body for implantation into a human body comprising the steps of:

placing at least one conductor coated with a layer of extrusion material on a mandrel; and

forming a lead body assembly that includes the at least one conductor coated with a layer of extrusion material; and

attaching at least one electrode to said at least one conductor.

41. (Previously Presented) The method as claimed in Claim 40 further comprising the steps of:

placing heat shrink tubing over the lead body assembly;

heating the lead body assembly to melt the extrusion material in the lead body assembly;

compressing the melted extrusion material around the at least one conductor coated with a layer of extrusion material in the lead body assembly;

cooling the lead body assembly to form the lead body; and

removing the heat shrink tubing from the lead body.

42. (Currently Amended) A lead body for implantation into a human body comprising a plurality of conductors in which each conductor of the plurality of conductors is coated with a layer of extrusion material, wherein each conductor of said plurality of conductors is coupled to an electrode.

43. (Previous Presented) A lead body as claimed in Claim 42 further comprising an inner layer of extrusion material placed adjacent to the plurality of conductors that are coated with a layer of extrusion material.

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44. (Previous Presented) A lead body as claimed in Claim 43 further comprising an outer layer of extrusion material placed adjacent to the plurality of conductors that are coated with a layer of extrusion material.